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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,359	04/11/2002	Zeger Debyser	522-1764	6288

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BARNES & THORNBURG
P.O. BOX 2786
CHICAGO, IL 60690-2786

EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,359

Applicant(s)

DEBYSER ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004 and 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to paper filed 10/1/04.

Claims 105-112 are under consideration in this action.

Rejections Withdrawn

Claims 83-87 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the claims are precisely defined by their GC content. These claims were canceled. Applicant's arguments have been fully considered and found persuasive as applied to the new claims.

Rejections Maintained or Necessitated By Amendment

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 105-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Applicant argues that percent GC is not an inherent property, that non-preferred – referred has been amended, level of activity of level of expression and is explained in the specification, and that it is clear what the protein encoded is.

Applicant's arguments have been fully considered and found persuasive in part.

The phrase "when referred to the eukaryotic cell" is still not clear. Does Applicant mean when expressed in (the, a, said) eukaryotic cell?

In claims 110 and 112, the metes and bounds of the term homologue are not clear. It is not clear what defines homologues of synthetic sequences. The reference to homologues in the specification page 13, lines 28 and 29, does not define the term.

Claims 105-109, and 111 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an integrase construct of SEQ ID#1, does not reasonably provide enablement for producing a detectable enzymatic activity all retroviral genes with a specific percentage of optimized codons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The Examiner does not see specific arguments for this rejection.

The rejection of record is maintained.

Claim Rejections - 35 USC § 102

Claims 105-109, and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Seed.

Claims 1, 3, and 6- 10 of Seed disclose a retroviral gag or pol gene or a region that encodes an integrase with varying levels of codons changed to preferred codons for expression in eukaryotic cells that have expression levels increased at least 200%.

Applicant argues that Seed does not show that expressed proteins have proper structural confirmation, that Seed does not work with enzymes, that the specification teaches an important aspect of the invention and its applications is the functionality of an expressed retroviral enzymatically active protein, and that Seed does not specifically disclose the ranges of GC claimed, and that the GC pair frequency is not disclosed in the prior art.

Applicant's arguments have been fully considered and not found persuasive.

The claims are drawn to a synthetic gene, not a protein or functionality of an expressed protein, or the confirmation of proteins. Seed does teach HIV enzyme proteins and the range taught by Seed encompasses the recited ones. The claims do not recite GC pair frequency. Applicant's previous arguments indicate that GC refers to percent GC and not pairs.

Thus, Seed anticipates the claimed invention.

Conclusion

SEQ ID# 1 is free of the prior art.

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No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
December 22, 2004



JAMES HOUSEL 12/24/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600